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Dated: July 13, 2009  
Electronic Signature for Kelly Y. Hwang: /Kelly Y. Hwang/

Docket No.: PLASSR 3.3-001  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Garrigue et al.

Application No.: 10/569,316

Group Art Unit: 1618

Filed: February 22, 2006

Examiner: J. M. Vu

For: SELF-NANOEMULSIFYING OILY  
FORMULATION FOR THE  
ADMINISTRATION OF POORLY  
WATER-SOLUBLE DRUGS

**RESPONSE TO RESTRICTION REQUIREMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Madam:

This communication is in response to the Office Action mailed June 12, 2009, setting forth a Restriction Requirement in the above-identified application. In the Office Action, the Examiner required restriction to one of the following inventions under 35 U.S.C. §121:

- I. Claims 1-16, drawn to a pharmaceutical composition.
- II. Claims 17-20, drawn to use of an anhydrous self-nanoemulsifying oily formulation.
- III. Claim 21, drawn to a method of treatment of taxoid-responsive diseases.

In response, Applicants hereby elect the invention of Group I, corresponding to claims 1-16. Applicants reserve the

right to file a divisional application corresponding to the non-elected claims.

In addition, the Examiner stated that the application contains claims directed to more than one species of the generic invention, and required the Applicants to elect a single disclosed species.

The Examiner stated that more than one species of the therapeutic agent recited in the claims are as follows:

- Anti-fungal drugs
- Anti-viral drugs
- Antibiotic drugs
- Anti-inflammatory drugs
- Anti-cancer drugs
- Analgesics
- Antidepressants
- Antipsychotics
- Hormones
- Antacids
- Coronary vasodilators
- Cerebral vasodilators
- Psychotropics
- Antineoplastics
- Stimulants
- Anti-histamines
- Vasodilators
- Anti-arrythmics
- Anti-hypertensive drugs
- Vasoconstrictors
- Anti-migraine drugs
- Anti-coagulant drugs
- Anti-thrombotic drugs
- Anti-pyretics
- Hypnotics
- Sedatives
- Anticonvulsants
- Anti-epileptics
- Neuromuscular drugs
- Drugs acting on central nervous system
- Hyperglycemic agents
- Hypoglycemic agents
- Diuretics
- Anti-obesity drugs
- Anabolic drugs
- Anti-uricemic drugs
- Immunosuppressant drugs

The Examiner also stated that more than one species of the enhancer recited in the claims are as follows:

- Cytochrome P450 2C8 inhibitors
- Cytochrome P450 3A4 inhibitors
- Multidrug resistance inhibitors
- Pgp inhibitors
- Non specific inhibitors

In response, Applicants hereby elect the species "anti-cancer drug" as the therapeutic agent, and "Pgp inhibitor" as the enhancer. The claims corresponding to this election are claims 1-10 and 12-16.

In the event any fee is due in connection with the present response, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: July 13, 2009

Respectfully submitted,

Electronic signature:

/Kelly Y. Hwang/

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